

RESPONSE UNDER 37 C.F.R. § 1.116  
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### **REMARKS**

Claims 35, 48, 55, and 56 are pending in the instant application. Claims 1-34, 36-47, and 49-54 were previously canceled. Claims 57 -68 are added by this amendment. In the Office Action mailed March 3, 2004, the Examiner withdraws allowance of claims 35, 48, 55, and 56 and rejects those claims.

By virtue of the amendments to the claims presented above, claims 35, 48, 55, and 56 are amended. Based on the amendments and remarks made herein, Applicants respectfully request that the rejections be withdrawn and that the application be passed to allowance.

#### **1. Remarks on Paragraph 3 of the Office Action mailed on March 3, 2004**

In paragraph 3 of the Office Action mailed on March 3, 2004, the Examiner rejects claim 35 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 5,273,521 issued to Peiler et al. (hereinafter "the Peiler patent").

Claim 35 as amended is directed to an absorbent device adapted to deliver a therapeutic agent to a user having a vaginal epithelium, the device including a generally cylindrical body having a proximal end and a distal end and adapted to be positioned entirely within the user. The body includes an absorbency zone adjacent the distal end, wherein the absorbency zone includes absorbent material; an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has a surface adapted to contact the vaginal epithelium; and a formulation including a therapeutic agent positioned substantially adjacent the surface and substantially within the application zone, wherein the formulation including a therapeutic agent includes a hydrogel material or a foam component.

The Peiler patent does not disclose an absorbent device including an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has a surface adapted to contact the vaginal epithelium. As defined by the Applicant in the instant application on page 10, lines 11-14, the proximal end is the string end, and the distal end is end closest to the cervix. The Examiner has incorrectly identified these ends in Paragraph 3. Nevertheless, the medicament 20 of the Peiler patent extends from one end of the tampon to the other and is not positioned substantially within an application zone. In addition, the surface 24 of the Peiler patent is internal to its disclosed tampon, and thus is not adapted to contact the vaginal epithelium. Further, the Peiler patent discloses a tampon with an outer surface 26, but the medicament 20 of the Peiler patent is not positioned substantially adjacent that surface.

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**2. Remarks on Paragraph 4 of the Office Action mailed on March 3, 2004**

In paragraph 4 of the Office Action mailed on March 3, 2004, the Examiner rejects claims 48 and 55 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 2,110,962 issued to Munro (hereinafter "the Munro patent").

Claim 48 as amended is directed to a method for producing a device for delivering a therapeutic agent to a user having a vaginal epithelium, the method comprising manufacturing a tampon having a generally cylindrical body with a distal end, a proximal end, a longitudinal axis, an absorbency zone adjacent the distal end, and an application zone adjacent the proximal end, wherein the body is adapted to be positioned entirely within the user, wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface, wherein the application zone has an application zone surface, and wherein the manufacturing act includes manufacturing the body from a material; and locating a formulation including a therapeutic agent substantially adjacent the application zone surface and substantially within the application zone, including applying the formulation including a therapeutic agent to the material before the body is manufactured.

First, the Munro patent does not disclose manufacturing a tampon having a generally cylindrical body. As stated at page 2, col. 2, lines 67-73, the Munro patent discloses a "pessary compris[ing] a head portion of generally spherical contour provided with a cup-shaped recess or recess (sic) 2 on the upper portion . . . which recess is adapted to receive the cervix or other organ . . ." The pessary of the Munro patent is not generally cylindrical. In fact, Munro specifically differentiates between the spherical head portion 1 (page 2, second column, lines 67-68) and the cylindrical portion 4 (page 3, first column, lines 4-5). Redesigning the pessary of the Munro patent to be generally cylindrical would defeat its stated purpose of receiving the cervix.

In addition, the Munro patent does not disclose an absorbency zone that has an absorbency zone surface adapted to contact a vaginal epithelium and absorbent material extending from a longitudinal axis to the absorbency zone surface in conjunction with a formulation including a therapeutic agent substantially within an application zone. The Munro patent discloses in Fig. 6 absorbent material 6 within a housing 1, 4, which does not have absorbent material extending from a longitudinal axis to an absorbency zone surface adapted to contact a vaginal epithelium. The Munro patent at page 3, col. 2, lines 12-15 discloses a device made from gauze or like absorbent material saturated with sterilizing matter. Because the entire device thus contains the sterilizing matter, the Munro patent device also does not have a formulation including a therapeutic agent substantially within an application zone.

It should be noted that the Munro patent does not disclose a method for producing a device for delivering a therapeutic agent to a user having a vaginal epithelium, the method comprising

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manufacturing a tampon having a generally cylindrical body with a distal end, a proximal end, a longitudinal axis, an absorbency zone adjacent the distal end, and an application zone adjacent the proximal end, wherein the body is adapted to be positioned entirely within the user, wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface, wherein the application zone has an application zone surface, and wherein the manufacturing act includes manufacturing the body from a material; and locating a formulation including a therapeutic agent substantially adjacent the application zone surface and substantially within the application zone, including applying the formulation including a therapeutic agent to the material before the body is manufactured. Even extensive attempts to redesign the Munro patent embodiments fall short of disclosing the subject matter claimed in the instant application.

Claim 55 as amended is directed to an absorbent device adapted to deliver a therapeutic agent to a user having a vaginal epithelium, the device including a generally cylindrical body having a proximal end, a longitudinal axis, and a distal end. The body includes an absorbency zone adjacent the distal end, wherein the absorbency zone includes absorbent material, and wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface; an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has an application zone surface, and wherein the application zone consists essentially of non-absorbent material; and a formulation including a therapeutic agent positioned substantially adjacent the surface and substantially within the application zone.

As defined by the Applicant in the instant application on page 10, lines 11-14, the proximal end is the string end, and the distal end is end closest to the cervix. The Examiner has incorrectly identified these ends in the discussion of the Munro patent with respect to claim 55 in Paragraph 4. As a result, Fig. 3 in the Munro patent does not have an absorbency zone adjacent the distal end. Likewise, the surface 2 of the Munro patent is not spaced apart from the distal end, the surface 2 is at the distal end. Thus, the pessary of the Munro patent does not have an application zone spaced apart from the distal end, and does not have an absorbency zone adjacent the distal end.

The Munro patent does not disclose an absorbent device having a generally cylindrical body. As stated at page 2, col. 2, lines 67-73, the Munro patent discloses a "pessary compris[ing] a head portion of generally spherical contour provided with a cup-shaped recess or recess (sic) 2 on the upper portion . . . which recess is adapted to receive the cervix or other organ . . ." The pessary of the Munro patent is not generally cylindrical. In fact, Munro specifically differentiates between the spherical head portion 1 (page 2, second column, lines 67-68) and the cylindrical portion 4 (page 3, first column, lines

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4-5). Redesigning the pessary of the Munro patent to be generally cylindrical would defeat its stated purpose of receiving the cervix.

In addition, the Munro patent does not disclose an absorbency zone that has an absorbency zone surface adapted to contact a vaginal epithelium and absorbent material extending from a longitudinal axis to the absorbency zone surface in conjunction with a formulation including a therapeutic agent substantially within an application zone. The Munro patent discloses in Fig. 6 absorbent material 6 within a housing 1, 4, which does not have absorbent material extending from a longitudinal axis to an absorbency zone surface adapted to contact a vaginal epithelium. The Munro patent at page 3, col. 2, lines 12-15 discloses a device made from gauze or like absorbent material saturated with sterilizing matter. Because the entire device thus contains the sterilizing matter, the Munro patent device also does not have a formulation including a therapeutic agent substantially within an application zone.

It should be noted that the Munro patent does not disclose an absorbent device adapted to deliver a therapeutic agent to a user having a vaginal epithelium, the device including a generally cylindrical body having a proximal end, a longitudinal axis, and a distal end. The body includes an absorbency zone adjacent the distal end, wherein the absorbency zone includes absorbent material, and wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface; an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has an application zone surface, and wherein the application zone consists essentially of non-absorbent material; and a formulation including a therapeutic agent positioned substantially adjacent the surface and substantially within the application zone. Even extensive attempts to redesign the Munro patent embodiments fall short of disclosing the subject matter claimed in the instant application.

### 3. Remarks on Paragraph 7 of the Office Action mailed on March 3, 2004

In paragraph 7 of the Office Action mailed on March 3, 2004, the Examiner rejects claim 56 as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 2,110,962 issued to Munro (hereinafter "the Munro patent").

Claim 56 as amended is directed to a method for producing a device for delivering a therapeutic agent, the method including manufacturing a tampon having a generally cylindrical body with a distal end, a proximal end, a longitudinal axis, an absorbency zone adjacent the distal end, and an application zone adjacent the proximal end, wherein the application zone has an application zone surface, wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface; compressing

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the body; and locating a formulation including a therapeutic agent substantially adjacent the application zone surface and substantially within the application zone after the body is compressed.

The Munro patent does not disclose manufacturing a tampon having a generally cylindrical body. As stated at page 2, col. 2, lines 67-73, the Munro patent discloses a "pessary compris[ing] a head portion of generally spherical contour provided with a cup-shaped recess or recess (sic) 2 on the upper portion . . . which recess is adapted to receive the cervix or other organ . . ." The pessary of the Munro patent is not generally cylindrical. In fact, Munro specifically differentiates between the spherical head portion 1 (page 2, second column, lines 67-68) and the cylindrical portion 4 (page 3, first column, lines 4-5). Redesigning the pessary of the Munro patent to be generally cylindrical would defeat its stated purpose of receiving the cervix.

In addition, as defined by the Applicant in the instant application on page 10, lines 11-14, the proximal end is the string end, and the distal end is end closest to the cervix. The Examiner has incorrectly identified these ends in part of the discussion of the Munro patent with respect to claim 56 in Paragraph 7. The cylindrical portion 4 and the surface 2 (in Fig. 7) cannot both be at the proximal end of the pessary in the Munro patent. The surface 2 is at the distal end of the pessary in Figure 7.

Further, the reference to "compressible" at page 2, col. 2, lines 24-25 refers not to the manufacture of the pessary, nor even the structure of the entire pessary, but to the structure of a portion such as that shown in Fig. 5 that can extend or contract "to receive increasing quantities of secretion." (page 3, col. 1, lines 65-69) There is no teaching whatever to compress the pessary as a whole or in part in its manufacture. In addition, Munro requires that "there be some definite rigid members about which or upon which the more variable parts may be supported." (page 2, col. 2, lines 21-27) In other words, for one portion of the pessary to be "variable," it must have a rigid portion to act against. Again, there is no mention of compressing in the manufacture of a tampon.

Finally, the embodiment described in the Munro patent at page 3, col. 2, lines 12-15, which discloses a device made from gauze or like absorbent material saturated with sterilizing matter, is exactly the type of device described as a problem by the Applicant in the application Summary at page 2, lines 23-30. The Munro patent requires the gelatine to melt away from the pessary before the gauze will be available to absorb menses (page 2, col. 1, lines 34-36). As identified by the Applicant, such devices are ineffective because any medicament tends to absorb into the absorbent along with the menses. The flow of menses does not conveniently wait until the gelatine/medicament has melted and the medicament has transferred to the user. Locating medicament as in the Munro patent tends to decrease the effectiveness of both the absorbent and the medicament. Nothing disclosed in the Munro patent solves this problem.

It should be noted that the Munro patent does not disclose a method for producing a device for delivering a therapeutic agent, the method including manufacturing a tampon having a generally

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cylindrical body with a distal end, a proximal end, a longitudinal axis, an absorbency zone adjacent the distal end, and an application zone adjacent the proximal end, wherein the application zone has an application zone surface, wherein the absorbency zone has an absorbency zone surface adapted to contact the vaginal epithelium and absorbent material extending from the longitudinal axis to the absorbency zone surface; compressing the body; and locating a formulation including a therapeutic agent substantially adjacent the application zone surface and substantially within the application zone after the body is compressed. Even extensive attempts to redesign the Munro patent embodiments fall short of disclosing the subject matter claimed in the instant application.

Therefore, Applicant respectfully submits that amended claims 35, 48, 55, and 56 are patentable over the references cited by the Examiner. Similarly, added claims 57-68 depend from these patentable independent claims and are likewise patentable.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of pending claims 35, 48, 55, and 56. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-8863.

The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account. A duplicate of this sheet is provided.

The undersigned may be reached at: 920-721-8863.

Respectfully submitted,  
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By: 

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CERTIFICATE OF FACSIMILE TRANSMISSION

I, Mary L. Roberts, hereby certify that on September 3, 2004, this document is being transmitted via facsimile to: Commissioner for Patents, Right Fax No. 703-872-9306.

By: Mary L. Roberts  
Mary L. Roberts